



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,983	12/10/2003	Thomas J. Holman	S63.2B-10888-US01	8501
490 7590 10/24/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 10/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/732,983	Applicant(s) HOLMAN ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11,12,14 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10,16-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the RCE filed 8/13/2007 in which claims 1, 18-20 and 23 were amended. Currently claims 1-12, 14 and 16-29 are pending examination in this application with claims 8-9, 11-12, 14 and 28 being withdrawn from a previous election restriction.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 17-25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wijay et al. (4,921,483). Wijay et al. discloses an angioplasty catheter.

Regarding claims 1-3, 17-25 and 29, Wijay et al. discloses a catheter comprising: a proximal portion, a distal portion, the distal portion terminating at a distal end, a shaft (20) with a stepped down portion (26), the shaft having a proximal portion, a distal portion, the distal portion terminating at a distal end, and a conduit there through (lumen of 26), and a distal tip layer (72), the distal tip layer (72) being in the form of a tube (Figures 3 and 5) and being positioned about the distal portion of the shaft, the distal tip layer having a proximal end and a distal end, wherein the distal end of the distal tip layer (72) extends distally to at least the distal end of the shaft (26) (from about 32-74) and forms at least a portion of the distal end of the catheter, the catheter further

Art Unit: 3763

comprising a medical balloon (28), the balloon having a body portion positioned between a proximal waist and a distal waist, wherein the distal waist is connected to the distal portion of the shaft and is positioned at least adjacent to the proximal end of the distal tip layer which is stepped to receive the distal waist, and wherein the distal tip layer is circumferentially between the distal and the shaft (Figure 3), such that the distal waist is not in contact with the shaft and wherein the shaft (26) extends distally beyond the distal waist (of 28) with the distal tip (72) extending distally beyond the shaft (26) (cols 1-2) at a fixed distance (col 7, ln 40-70), wherein the distal waist and shaft are incompatible for thermal bonding because the two layers are not in contact with each other.

Claim Rejections - 35 USC § 102

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwab et al. (5,769,819). Schwab et al. discloses a catheter distal tip component.

Regarding claims 23-25, Schwab et al. discloses a catheter (5) comprising: a shaft (65), a first tubular layer (55) circumferentially about the shaft (65) and a second tubular layer (40) circumferentially about the shaft, the shaft and the first tubular layer being thermally bonded together, the first tubular layer having an inner side and outer side and being at least partially circumferentially between the second tubular layer (40) and the shaft (65), wherein the second tubular layer (40) and the shaft (65) are incompatible for thermal bonding because of the adhesive layer between the different layers (Figures 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 6-7 are rejected under 35 U.S.C 103(a) as being unpatentable over Wijay et al. in view of Larson et al. (6,048,338). Wijay et al. meets the claim limitations as described above except for a spiral cut layer.

However, Larson et al. teaches a catheter with a spiral cut transition member with multiple layers.

Regarding claims 4 and 6-7, Larson et al. teaches catheter (200) with a multi-layer construction comprising a spiral cut member (126) (Figure 5).

At the time of the invention, it would have been obvious to add the spiral cut member of Larson et al. to the system of Duchamp in order to improve catheter flexibility and catheter tracking (col 2, ln 1-25). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled

in the art would have combined the teachings in the references in light of the disclosure of Larson et al. (see abstract).

Claim Rejections - 35 USC § 103

Claims 5 and 26-27 are rejected under 35 U.S.C 103(a) as being unpatentable over Wijay et al. (or Schwab et al.). Wijay et al. (or Schwab et al.) meets the claim limitations as described above except for the specific disclosed materials .

Regarding claims 5 and 26-27, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Wijay et al. (or Schwab et al.) with the materials as claimed by Applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments with respect to claims 1-7, 10, 16-27 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/22/07

CDK
Christopher D. Koharski
AU 3763

N. Lucchesi
NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700